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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,644	02/11/2002	Debra Hudson	MXI-211	6293
959	7590	04/20/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			BELYAVSKIY, MICHAEL A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/073,644

**Applicant(s)**

HUDSON ET AL.

**Examiner**

Michail A Belyavskyi

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 52-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 52-100 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment, filed 03/23/04 is acknowledged.

Claims 52- 100 are pending.

### ***Restriction Requirement***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 52-69 , 85, 88 and 89 drawn to an isolated human monoclonal antibody and a composition comprising said antibody, classified in Class 530, subclasses 387.9 and 388.15.
  - II. Claim 70, drawn to a transgenic nonhuman animal, classified in Class 800, subclass 8.
  - III. Claim 71, drawn to a method of producing the antibody, classified in Class 424, subclasses 141.1.
  - IV. Claims 72-79 and 86 drawn to a bispecific or multispecific molecule comprising a portion which binds to a target antigen other than CD89 and composition comprising said molecule, classified in Class 530, subclass 387.3.
  - V. Claims 80-84 and 87 drawn to a molecule conjugate, comprising the human antibody linked to an antigen and a composition comprising said conjugate, classified in Class 530, subclass 387.1.
  - VI. Claim 90 , drawn to an immunotoxin, classified in Class 530, subclass 391.7.
  - VII. Claims 91-96, drawn to a method of inhibiting growth of a cell, comprising contacting the cell with an effective amount of bispecific or multispecific molecule classified in Class 424, subclass 193.1.
  - VIII. Claims 97-98 , drawn to a method treating or preventing a disease, comprising contacting administering an isolated human monoclonal antibody that specifically binds to CD89 classified in Class 424, subclass 139.1
  - IX. Claims 99, drawn to a method of detecting the presence of CD89, classified in Class 435, subclass 7.1.

Art Unit: 1644

X. Claim 100 drawn to an expression vector, comprising a nucleotide sequence encoding the variable regions of a human monoclonal antibody classified in Class 435, subclass 320.1.

3. Groups I- II, IV -VI and X are different products. An isolated antibody, a transgenic nonhuman animal, a bispecific or multispecific molecule, a molecule conjugate, an expression vector and immunotoxin differ with respect to their structures and physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct.

4. Groups III and VII – IX are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.

5. Groups I and VII-IX are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used for affinity purification, in addition to recited methods of inhibiting treating and detecting.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

8. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

9. If Group I is elected, applicant is required to elect one specific isolated human monoclonal antibody, comprising one specific sequence for each CDR1, CDR2 and CDR3 of heavy chain and one specific sequence for each CDR1, CDR2 and CDR3 of light chain, selected from the group recited for example in claims 56 –59.

Art Unit: 1644

These species are distinct because their structure, physicochemical properties and binding epitopes are different. The examination of species would require different searches in the scientific literature.

10. If Group IV is elected, applicant is required to elect one specific bispecific or multispecific molecule wherein the specific antigen is selected from the group recited in claim 79.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

10. If Group V is elected, applicant is required to elect one specific conjugate molecule wherein the specific antigen is selected from the group recited in claim 84.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

11. If Group X is elected, applicant is required to elect one specific expression vector wherein one specific heavy chain nucleotide sequence and one specific light chain nucleotide sequence is selected from the group recited in claim 100.

These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Art Unit: 1644

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to Jeanne M DiGiorgio on 4/9/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 19, 2004

  
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